UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS et al.,
Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
Defendant.

Civil Action No. 16-cv-11985-IT

PLAINTIFFS' RESPONSE TO FDA'S SUPPLEMENTAL FILING

FDA's filing confirms the availability of statutory and regulatory mechanisms that an agency may use to seek expedited review from OMB when necessary. *See* ECF No. 48. These provisions recognize the need to accelerate information gathering and rulemaking to avoid harm to the public and to meet statutory or court-ordered deadlines. There is no suggestion in the record, however, that FDA has made any effort to expedite OMB review during what still remain preliminary stages of its long-overdue curative rulemaking. *See* ECF No. 35-1; ECF No. 42.

It was only when there was a looming threat of judicial intervention that FDA and OMB suddenly began to move things along. FDA reported to the Court two days before oral argument that the agency was still (apparently passively) awaiting OMB approval for two information-gathering projects. See ECF 42 at 1. Just minutes before oral argument began, FDA was due to speak to OMB to answer its questions, ask about the status of the two pending matters and, presumably, to urge OMB to approve FDA's proposals. ECF No. 47 (Transcript) at 38-39. Only after the Court noted at the conclusion of the motion hearing that "it appears that some court intervention may well be necessary," ECF No. 47 at 59, was FDA suddenly able to obtain OMB approval and launch its information gathering. ECF No. 48 at 4.

None of the new facts that have come to light since the summary judgment papers were completed provide any basis for the Court to dismiss the Complaint; instead, FDA's course of conduct over the past six months reinforces the need for judicial intervention. The Court should find that FDA has both unlawfully withheld and unreasonably delayed its graphic warnings rule, grant the Plaintiffs' Motion for Summary Judgment, deny FDA's Motion for Summary Judgment, and promptly turn to the question of how the Court can most effectively compel agency action, as required by the APA.

Respectfully submitted,

/s/ Scott P. Lewis

Scott P. Lewis (BBO #298740)
Jessica A. Wall (BBO #689177)
ANDERSON & KREIGER LLP
50 Milk Street, 21st Floor
Boston, MA 02109
617-621-6500
slewis@andersonkreiger.com

Mark E. Greenwold (*pro hac vice*)
Dennis A. Henigan (*pro hac vice*)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I (Eye) Street, N.W., Suite 1200
Washington, DC 20005
202-296-5469
mgreenwold@tobaccofreekids.org

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Certificate of Service

I hereby certify that this document filed through the ECF system was sent electronically to all counsel of record on February 2, 2018.

/s/ Scott P. Lewis